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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,671

05/15/2001

Takahiro Ochi

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01/10/2005

FOLEY AND LARDNER

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/854,671

Applicant(s)

OCHI, TAKAHIRO

Examiner

Sandra Saucier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-22, 25-29 and 34-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-22, 25-29 and 34-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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#### DETAILED ACTION

Claims 16-22, 25-29, 34-43 are pending and are considered on the merits.

#### *Claim Rejections - 35 USC § 112*

Claims 16-22, 25-29, 34-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 25 now state that the biomember comprises a compact member and a porous member which are integrally made of a calcium phosphates sintered body. This appears to imply that both the compact and porous members are made of calcium phosphate. However, claim 17 then recites that the compact member is metal or ceramic. Thus, the claim language is indefinite and does not define the structure and interrelationship of the compact and porous members.

Claim 36 now recites that the porous body comprises ...and a skeletal part...". The structure of the item produced cannot be understood because the relationship between the members of the structure is not clear. What is the "skeletal" part and is it the same as the compact member?

A structure has parts which are distinct from one another and which have relationships to one another. The claimed structure does not fulfill this basic requirement.

Claims 16-22, 25-29, 34-43 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

amount of guidance and working examples

The specification discusses the characteristics that the final product should have, but fails to include any working example or description of the production of the article. The components of the slurry are said to be calcium phosphate with a stated diameter and a cross-polymerisable resin. The ratio of resin and calcium phosphate and amounts to be made into a slurry are not given even in general terms. A bubbling step is preferred to form pores in the slurry. However, no parameters for foaming are taught such as the apparatus set up for bubbling, the rate and duration of gas flow, the density of the slurry, rate of stirring, etc., but foaming by application of a gas or by stirring appears to be critical to the final pore diameter (page 17, second full paragraph). No length of time of drying or sintering is given. In fact, the thin description appears to be directed mainly towards desired characteristics of the size and quality of the interconnecting pores of the final article, not the disclosure of the processes for obtaining them.

#### nature of the invention

The invention is directed towards the manufacture of an article for implantation and the article itself with very particular pore sizes and configurations.

#### state of the prior art and unpredictability

The state of the art regarding an implantable article with disclosed processes for forming interconnecting pores of controlled sizes appears to be very limited. The cited prior art of US 6,340,648 appears to be the only prior art discussing pore size and interconnectivity. Since the instant application asserts the novelty of the article manufactured and argues that the processes disclosed in the prior art of WO 93/04013 and US 6,340,648 form distinct products from the instant product, a description of the novel process sufficient to allow those of skill in the art to replicate the product is essential. Particular attention is drawn to applicant's arguments filed 4/9/04 where applicant states "In addition to the differences based on the different processing temperatures, a porosity of the porous body, a pore diameter, a degree of communication of the pores are different, *largely depending on how the slurry is stirred and the*

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*degree of gas contained therein.* The types of pores are very important features for preferred embodiment of the presently claimed invention.”. Applicant has not disclosed any parameters for the process which produces this argued critical element.

#### breadth of the claims

The claims are directed to biomembers made of a calcium phosphate material with the specified pore size, porosity and interconnectivity.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

#### *Response to Arguments*

Applicant argues that cited prior art US '648 provides evidence that those of skill in the art know how to select the foaming conditions to obtain a sintered article with a desired pore size. However, the cited prior art does not teach general principles only the specific parameters associated with the prior art product. This argument appears, on the one hand, to admit that the porosity and interconnectivity of the prior art product is the same as their product, and therefore, the prior art teaches their admittedly critical elements of porosity and the characteristics of the interconnection of the pores which characteristics have been, on the other hand, argued to distinguish the instant product from the prior art. See the response of 4/9/04, page 12 where it is stated that US'648 does not teach or suggest a biomember “having large pores having a size larger than the mean pore diameter have a plurality of communicating pores, so that the body fluid can be supplied in any directions.”.

Applicant presents a example in their response to supposedly teach how to make the claimed product. However, it is a belated attempt. Enablement, that is, the teaching of how to make and use, must be present in the

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specification when filed. The example in the response appears to be substantially identical to the process disclosed in example 1 of US '648. If the newly disclosed process is the same or essentially similar to the prior art process, one can reasonably assume that the product is the same. In the light of the present and persistent confusion, and lack of working example in the body of the specification and lack of clarity in the claims, both the enablement and prior art rejections are maintained.

***Claim Rejections – 35 USC § 103***

Claims 16–22, 25–29, 33–43 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,340,648 [A] in combination with Chistolini *et al.* [U] or Itokazu *et al.* [V].

The claims are interpreted to be directed to an article comprising a compact body of porosity of 0–15% and a porous body (both?) of sintered calcium phosphate, the porous body having globular pores with a porosity of 55–85%, a mean pore diameter of 50–800 microns, including a plurality of large pores having at least three communicating pores of not less than 5 micron diameter and at least one of the communicating pores having a diameter of 25 microns, wherein the total of the open area is not more than 50% of the pore area, and the pores contain various cells? and a method of making the article.

The references are relied upon as explained below.

US 6,340,648 discloses an implant comprising a dense part and a porous part where the outer calcium phosphate sintered part has a porosity of 55–90% with a pore diameter of 150 microns or more and interconnecting pores. The article is formed by foaming with a resin and sintering. The article may be impregnated with a drug, see entire patent.

Itokazu *et al.* disclose that porous hydroxyapatite may be loaded with antibiotic or anticancer drugs prior to implantation.

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Chistolini *et al.* disclose that porous hydroxyapatite may be loaded with cells prior to implantation.

The addition of cells into the porous implant disclosed in US 6,340,648 would have been obvious when taken with Itokazu *et al.* or Chistolini *et al.* who disclose such an addition. Also, US '648 disclose the incorporation of medicine into the pores in column 3, line 34.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition of cells to the porous implant in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

#### ***Response to Arguments***

Applicant's arguments filed 10/12/04 have been fully considered but they are not persuasive.

Applicant states that US 6,34,648 does not teach or suggest features of the presently claimed invention such as the larger pores having a plurality of communicating pores to permit free flow of body fluid.

US'648 in example 1 states that the hydroxyapatite sintered porous body has an average pore diameter of 200 micrometers and a average diameter of communicating parts of 70 micrometers. This appears to be within the claim limitations of a mean pore diameter of 50–800 micrometers with a communicating pore diameter of not less than 25 micrometers. While the reference appears to be silent with regard to the presence of a plurality of large pores having a size larger than the mean pore diameter, a mean, by definition is an average, which necessarily must include pores larger than the mean as well as smaller than the mean. A plurality by definition may be satisfied if only two pores are larger than the mean. Since the process used to make the article

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in US'648 is the same or very similar to the instantly disclosed process, the products are assumed to be the same in the absence of evidence to the contrary, even though all of the characteristics of the product are not disclosed.

Applicants argue that claims 16 and 25 recite a biomember which includes a compact (dense) member and a porous member integrally formed. In contrast, applicants argue that US'648 does not teach this combination of compact and porous members because the entire sintered body of US'648 comprises a porous member.

Please look at col. 6, lines 20–46 of US '648 where it appears that an embodiment contains a “newly adhered” layer may be provided which is porous or dense. The mechanical strength can be improved. Thus, applicants arguments that US '648 does not disclose a more dense portion and a more porous portion of the article is not persuasive. Admittedly, the poor quality of the translations of both the instant specification/claims and US '648 lead to real difficulties in interpretation of both.

The claimed invention must have a CLAIMED structural difference between it and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

### *Conclusion*

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'S. Saucier', written over a horizontal line.

Sandra Saucier

Primary Examiner

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January 5, 2005